EXHIBIT 21

ALFRED P. WEHNER, D.M.D., SC.D., CAND. MED.
DIPLOMATE, ACADEMY OF TOXICOLOGICAL SCIENCES
312 SAINT STREET
RICHLAND, WASHINGTON 99352

9/17/97

Mr.Michael R.Chudkowski
Manager, Preclinical Toxicology
J&J Consumer Products,Inc.
Skillman, NJ 08558-9418

Dear Mike:

There is a German saying which translates as follows:

"A true friend is not he who beguiles you with flattery
but he who discloses to you your mistakes
before your enemies discover them."

In this spirit I would like to volunteer a critique of the three CTFA response statements which you faxed me on September 11. Some of the wording leaves CTFA wide open to counter-attack. The most harmless response statement of the three is the one dated July 1,1992. It does not give the names of the authors and the title of the paper to which the response is being made. More important, I believe that different and/or additional more powerful statements along the lines of my critique faxed to Jerry McEwen, as far as applicable to the situation in 1992, would have put CTFA in a more advantageous tactical position. Several investigators have independently reported talc particles in ovarian tissue. Simply citing the Battelle study and stating that it "demonstrated that talc does not translate (sic!) through the cervix to the uterine cavity and beyond" does not address the problem, does not refute these findings, and therefore does not serve CTFA's best interest. All in all, in my opinion an inept response.

The problem with the response statement dated July 8,1992, is more serious. The last sentence in the second paragraph states: "Finally, human studies on talc and cancer in industrial settings have shown that industrial exposure to talc, both by skin contact and inhalation, even at levels thousands of times higher than lifetime consumer exposure, presents no significant risk." This statement is outright false. All an Epstein, a Kennedy, or one of their aides knowledgeable in matters talc, would have to do at a hearing (or any occasion, at that) to demolish the credibility of the talc industry is to refer to the studies by Kleinfeld et al, Thomas, and Thomas and Stewart!

Referring in a 1992 statement to a 1977 editorial in defense of one's position is not a very persuasive argument. Much can happen in 15 years.

509/375-0873 FAX 509/375-5693

Here, too, I believe that more powerful and better defendable arguments could and should have been made on behalf of the industry.

The response statement dated November 17, 1994, is just as bad. The second sentence in the third paragraph reads: "The workshop concluded that, although some of these studies suggested a weak association might exist, when taken together the results of the studies are insufficient to demonstrate any real association." This statement is also inaccurate, to phrase it euphemistically. At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer. Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary. This would be a particularly tragic misperception in view of the fact that the industry does have powerful, valid arguments to support its position.

The workshop did not conclude that "the results of the studies are insufficient to demonstrate any real association." As pointed out above, a "real" statistically significant association has been undeniably established independently by several investigators, which without doubt will be readily attested to by a number of reputable scientists/clinicians, including Bernard Harlow, Debra Novotny, Candace Sue Kasper, Debra Heller, and others. What the workshop panel did conclude was that (1) the results of the studies were ambiguous, inconsistent, contradictory and therefore inconclusive, (2) therefore hygienic use of cosmetic talc does not present a risk to the consumer. So why not use these powerful and irrefutable arguments (plus some of those along the lines of my fax to Rich) instead of questionable mush that leaves one vulnerable to counterattack? The following sentence states: "In addition there is no basis to conclude that talc is capable of migrating to the ovaries...". I submit that several reports, independently describing talc particles in/on ovarian tissue, along with other suggestive evidence (questionable as some of it might be) does provide a basis for just such a conclusion. My point is that such a complex and vexing issue cannot be credibly dismissed with one sweeping statement without any documenting references.

Mike, I realize that CTFA is not J&J. However, I believe that a defeat or embarrassment of CTFA also negatively affects J&J to some extent. As a consultant on a retainer I feel obligated to proactively act in the best interest of my client at all times, not only when I am approached with a specific assignment. This consideration alone motivated me to spend the time to bring my thoughts on this matter to your attention. I trust that in the process I did not step on anybody's toes.

Best regards

Al

EXHIBIT 22

NARRATIVE
TALC – NTP REGULATORY CHALLENGE

Good morning everyone. My name is Steve Jarvis and I am responsible for Health, Safety, and Environmental matters for Luzenac America.

This morning…it is my distinct pleasure to present to you a summary of our most recent regulatory challenge involving the National Toxicology Program and their review of talc for potential listing in the 10th Report on Carcinogens.

But first….for those who may not know exactly what we do …..I'd like to introduce you to Luzenac America.

SLIDE 1

Luzenac America is part of the Luzenac Group of Companies. Headquartered in France, Luzenac Group is the world largest commercial producer of talc products.

In North America…….. Luzenac America operates 4 talc mines and 8 talc milling operations…….We have large operations based in Ontario, Vermont, and Montana. …… Luzenac America is

1

headquartered in Denver Colorado where we also have our Research and Development Center.

Luzenac America mines and processes around a half-a-million tons per year generating approximately Redacted in sales.

Our major markets are talc sales to paper, polymers and paint markets……. and to a lesser degree, personal care products……

You might be interested to know that we produce all the baby powder for Johnson & Johnson – including the talc for their popular adult product, Shower-to-Shower. As an interesting aside, would you believe that Luzenac talc also goes into Cipro?? It's True!……

SLIDE 2

Our major regulatory challenge…… a challenge I might add that Luzenac absolutely could not afford to lose ……came from the NTP.

The NTP was authorized by the United States Congress to coordinate interagency toxicological testing and to publish the formal "Report on Carcinogens" which comes out about every 18-24 months…… To be listed in the RoC can be

devastating to a substance because of mandatory labeling requirements by OSHA and Proposition 65 in California.

In early 2000, NTP nominated talc for possible listing in the RoC because back in the early 1990's, the NTP published the results of a 2-year talc inhalation study on rats and mice and concluded that talc caused lung tumors in female rats……

More on that in a minute.

SLIDE 3

A listing of talc in the RoC would have devastating consequences for the talc market worldwide.

First of all……we would see a virtual immediate loss of our sales to the personal care market – around $10 Million in sales in the first year.

Secondly…….because of the carcinogenic labeling requirements, we would likely suffer a deterioration of sales in all markets….perhaps anywhere from 20% to 50% of all remaining sales by year-three.

Additionally, a listing in the U.S. by NTP would likely trigger a carcinogenic status for talc in Europe and the Far East.

And finally……. because of our consumer product exposure, civil litigation would likely skyrocket.

As I mentioned, simply devastating consequences.

SLIDE 4

Now realistically….. there are some health issues with talc. For nearly 20 years, epidemiologists have been finding a weak, but persistent statistical link between the hygienic use of talc and ovarian cancer. However……. the studies are weakened by no one being able to offer any feasible "causal" explanations as to how and why talc would cause ovarian cancer……..but not a multitude of other cancers in the human anatomy.

As I mentioned, there is the 1992 rodent study by NTP, which found lung tumors in female rats. However, many other leading experts discount this finding claiming the tumors were a result of lung overload - simply too much inert dust in the lungs triggering an traumatic auto-immune response from the rats.

And finally, there is the long-held public perception that all talc contains asbestos. And even if it

doesn't, they are so similar chemically, that talc probably behaves like asbestos.

So these are some of the primary issues and concerns that served as the backdrop for the NTP review.

SLIDE 5

Okay….so here's what happened.

NTP announces in early 2000 that talc is going to be review. While this announcement catches us off guard, we are not alarmed.

But then, in October of 2000, NTP issues their draft report on talc and announces that the first two formal reviews resulted in votes to list talc as a carcinogen. The combined vote was 13-2 to list.

The entire talc industry, as well as companies like J&J were absolutely, positively, unquestionably, flabbergasted……. We simply could not believe it.

But now we had only two months to prepare for the third NTP review meeting…… a public meeting of the influential Board of Scientific Counselors Subcommittee. This occurred in December of last

year and we achieved a very dramatic turnaround. The BSC subcommittee voted 7-3 ***not*** to list talc.

And finally……we fast-forward to this past June for the fourth and final review process. We see the NTP Executive Committee took the unprecedented action to actually ***"stop"*** the review process on talc and send it back to the beginning. They did this by deferring a final vote on talc.

And make no mistake about it, they knew if they proceeded with a listing nomination for talc, Luzenac America was going to challenge them in Federal Court……and as the facts lay out, NTP would likely lose. Of that we are fairly certain!

SLIDE 6

Our successful defense strategy was threefold.

First……we continued to work through the auspices of the CTFA – the Washington based trade association for the cosmetics industry. As you might imagine, Luzenac and Johnson & Johnson wield considerable influence on the talc subcommittee.

Secondly…….and this was our secret weapon, engage the services of the Washington based

Center for Regulatory Effectiveness, CRE. Since its formation in 1996 by several ex-high ranking officials in the OMB, CRE has grown into a nationally recognized…and relatively respected… regulatory watchdog organization. Federal agencies frequently come to them for assistance. CRE has also taken NTP to court.

And thirdly, we decided to be aggressive. This was a fight we simply could not lose. As such, we retained expert legal counsel to ensure we would have a solid foundation for a legal challenge if necessary…….it was the same firm which assisted CRE in their court battle with NTP……..and we also became very aggressive in our communication with NTP and other federal agencies. When didn't let the windows of "formal comment periods" become restrictive. We sent e-mails, faxes, overnight letters, and even telephones calls to key players in this battle….right up until hours before the final Executive Committee meeting.

And we believe these strategies paid-off.

SLIDE 7

While we certainly would have preferred a total victory – where NTP declared talc was not a human carcinogen……..we were relieved to at least get the review process "derailed" for now…….at least we have some "breathing space" to prepare a thorough, scientific defense of talc.

One of the issues we plan to focus on is demonstrating to NTP that virtually all of the epidemiology studies they previously used must be declared invalid for use in assessing talc "not containing asbestos". This will be an expansion of the "Fatal Flaw" defense Luzenac employed in the first review on talc.

Additionally, we believe the latest epidemiology study which IS valid with regard to talc quality….it's called the Gertig study……..and which also happens to be the largest study as well….. shows no increased risk of ovarian cancer. The significance of this study must be more heavily weighted than prior studies.

Any predictions at this point? Hard to say…but our hard fought victory this past year has given us some confidence and direction.

One last point……..lest we get complacent..
……regardless of what happens with NTP, we also have to keep an eye out for IARC. IARC reviewed talc back in 1986 and concluded there was insufficient evidence of talc carcinogencity in humans. We are hoping that this NTP activity doesn't stimulate IARC conduct an "end-run" around NTP declare talc a possible human carcinogen……..because I think you all know, we do not have the ability to become an active participant in that relatively "closed" process.

Thank you for your time.

EXHIBIT 23

Luzenac AMERICA
DENVER TECHNICAL CENTER
8985 E. NICHOLS AVE. • ENGLEWOOD, CO 80112 • USA

FACSIMILE

DATE:	March 26, 2002	FROM:	Richard J. Zazenski Director Product Safety
TO:	**Bill Ashton** **J&J**	PHONE	303-643-0404
		e-MAIL	rzazensk@luzenac.com
		FAX:	303-799-8926
cc:		Number of Pages: (including Cover Sheet)	**13 pages**

CONFIDENTIAL

Redacted

Luzenac group

Plaintiff's Exhibit No. P-27

Redacted

One other note – We've been successful thus far in fending off the NTP classification of talc as being a potential human carcinogen. But we must also keep an eye out for IARC. If they decide to re-review the status of talc because of all the ovarian epidemiology studies that have been published **since 1986**, IARC can surprise us all and decide to list "talc" as a potential human carcinogen. IARC reviews are not a public debate. Unlike NTP, IARC is answerable to no one politically (they are headquartered in Lyon, France of all places). As part of the World Health Organization, they act very independently to protect the citizens of this planet from "preventable" diseases. Their threshold for required medical evidence is predictably quite minimal.

You might want to counsel your management on this potential (and not to be too complacent about the status of talc).

Attached with this fax:
1 page on IARC (who they are).
2 pages on IARC's 1986 review of talc.
8 pages on their 1996 re-review of all forms of silica.

If any pages are unclear, please contact us.

the Luzenac group

HP OfficeJet G Series G85
Personal Printer/Fax/Copier/Scanner

Fax-History Report for
TECHNICAL ASSURANCE
(908)874-1126
Mar 26 2002 8:16am

Last Fax

Date	Time	Type	Identification	Duration	Pages	Result
Mar 26	8:15am	Sent	918593924202	1:06	1	OK

Result:
OK - black and white fax
Okay color - color fax

EXHIBIT 24

Luzenac AMERICA
DENVER TECHNICAL CENTER
8985 E. NICHOLS AVE. • ENGLEWOOD, CO 80112 • USA

INTEROFFICE MEMORANDUM

DATE: September 12, 2000

TO: R. Bernstein; J. Gauntt; R. Meli

CC:

FROM: Carl E. Kollmar

SUBJECT: Cosmetics Consultant Update

Richard Dodwell has filed his Progress Report. At this stage of the project he has completed all fax and telephone surveys and interviewed Luzenac's salespeople. At this time, there appears to be two problems with the market survey. First, several major body powder players have chosen not to respond to the surveys. This is an issue we need to consider. Second, Luzenac's major cosmetics distributor, WC&D, has not been interviewed. This is because Tom Grunstra, their in-house talc expert, has been out sick for several weeks.

Although we are missing input from several major players, I think there are some basic facts coming to light:

- Health is an issue to large body powder customers - a non-issue in other segments.
- The large volume body powder segment is not growing, although the decline of the past few years appears to have bottomed out. There is some growth in other segments.
- Other than soap bars, there appear to be limited growth opportunities (new markets/new products) for talc.

In my opinion, the large volume body powder portion of this business is not growing, it is price sensitive, there is aggressive competition (supplier and customer) and the omen of health concerns/liabilities hangs over it. This does not appear to be a market of opportunity for Luzenac at this time. Opportunities for growth appear to be limited to the soap bar segment – but the health/liability concerns remain.

In the details of Dodwell's report he identifies six major areas of interest: customer concerns, market growth, pricing, health concerns, competition and responsiveness to the survey.

Customer Concerns

There are three major concerns expressed by customers:

- The closing of a Montana mine has caused some disruption in the market. I assume they are referring to the closing of the Beaverhead Mine and the subsequent discontinuance of the Supreme and Olympic products. Some customers are still using old stockpiled material and have either not found or tested a suitable alternate.
- The technical service from Luzenac has declined, but the rest of the service package (quality, delivery, etc.) is well regarded.
- The health issue is taken seriously by large users (mainly body powder customers), and mostly ignored by the smaller segments and packagers.

Market Growth

- The market is growing in many sectors, but remaining static in the body powder applications. It appears that business in the body powder segment is merely shifting around, particularly amongst the packagers.
- There are no new applications for talc, except some work in soap bars. One soap bar company, P&G, appears ready to move to customer trials and market testing.
- Surface treated talcs hold some promise, but more application research by the talc suppliers is needed to demonstrate the merits.

Pricing

- Pricing is an issue to the large volume consumers, but not an issue with the smaller higher value segments where quality, technical service and product performance are the key requirements expected of a supplier.

Health Concerns

- Some companies label their products "Talc Free", but this is more for advertising and sales promotion than to address health concerns.
- The general public is not aware of any health issues regarding talc.

Competition

- Most of the decline in talc usage has occurred during the past 5 years and has bottomed out.
- There are no serious replacement threats to talc. "Wheat", "Oat Flour" and "Corn Starch" are not direct threats to talc since they were introduced under the "natural" and "organic" banners. Although they have replaced some talc, they have proved to be less than ideal and are now more often used in blends with talc.

- Not many customers expressed a preference for a talc supplier, but those that did mentioned Luzenac.

Responsiveness to Survey

Several companies would not respond unless the survey sponsor was revealed – this was the over-riding concern of those that did not respond to the surveys. In addition, large body powder users were reluctant to respond to this survey because of health liability concerns and, to a lesser extent, because their companies have a policy against revealing confidential information.

At this point, Dodwell has contacted 96 companies and achieved a level of response slightly above 35% - I think this is better than expected.

- Twenty-one companies were called twice with no response and appear to use their voice mail as a screening tool. They include Coty, Kolmar Labs, Maybelline, Revlon (NJ), Colgate Palmolive and Amway.
- Eleven companies generally refused to participate in the survey. This group included J&J, MK Packaging, Thornton, Lancome/Cosmair, Lander, Estee Lauder and Revlon (NC).

Obviously, we are missing an input from several of the major players. To get their input we would have to either reveal the survey sponsor and/or raise their level of interest to respond. Their level of interest can be raised by appealing to their self-interest – "if I don't respond to this survey it may affect my supply of talc". In either case, a personal visit may be required. As I mentioned during my update at the last Management Meeting, revealing the sponsor or raising their level of interest is a double-edged sword – it either brings forth the desired response out of self-interest, or it generates a concern over the supplier's viability and loyalty to the market. It could cause them to consider other talcs or talc alternatives. At this point, I would recommend that Dodwell make no further extraordinary efforts to pursue those who are not responding. This can be a topic of discussion when Dodwell presents his findings at the October 5th meeting in Denver.

EXHIBIT 25

to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food. Third, these amendments to this health claim will ensure that scientifically sound nutritional and health information regarding the benefits of fruit and vegetable intake and reduction of CHD risk can be provided to consumers as soon as possible. The past few editions of the DGA have been moving away from a focus on total fat and have instead communicated to consumers the need to focus on type of fat consumed instead of total amount of fat. Recent editions of the DGA have also encouraged increased intake of fruits and vegetables for a healthful diet. Prompt issuance of an interim final rule that reflects the current recommendations is necessary for consumers to be able to have the most current information on nutrition and diet. Consumers will be better able to construct healthful diets if they have prompt access to information that is consistent with the current recommendations on fat content and on consumption of fruits and vegetables. Therefore, we are using the authority in section 403(r)(7)(A) of the FD&C Act to issue an interim final rule amending the general requirements for the health claim for dietary saturated fat and cholesterol and risk of CHD and to make the interim final rule effective immediately.

This regulation is effective upon publication in the **Federal Register**. We invite public comment on this interim final rule. We will consider modifications to this interim final rule based on comments made during the comment period. We will address comments and confirm or amend the interim final rule in a final rule.

X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov*. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Liu, S., J.E. Manson, I.M. Lee, et al. "Fruit and Vegetable Intake and Risk of Cardiovascular Disease: The Women's Health Study." *The American Journal of Clinical Nutrition*, 72: 922–928, 2000.

2. Appel, L.J., T.J. Moore, E. Obarzanek, et al. "A Clinical Trial of the Effects of Dietary Patterns on Blood Pressure." DASH Collaborative Research Group. *The New England Journal of Medicine*, 336: 1117–1124, 1997.

3. U.S. Department of Health and Human Services and U.S. Department of Agriculture. "Dietary Guidelines for Americans, 2010. 7th Edition," 2010. Available at *http://health.gov/dietaryguidelines/2010/*.

4. "Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report." *Circulation*, 106: 3143–3421, 2002.

5. U.S. Department of Health and Human Services and U.S. Department of Agriculture. "2015–2020 Dietary Guidelines for Americans, 8th Edition," December 2015. Available at *http://health.gov/dietaryguidelines/2015/guidelines/*.

6. U.S. Department of Health and Human Services and U.S. Department of Agriculture. "Nutrition and Your Health, Dietary Guidelines for Americans," 2000. Available at *http://health.gov/dietaryguidelines/2000.asp*.

7. U.S. Department of Health and Human Services and U.S. Department of Agriculture. "Dietary Guidelines for Americans, 2005. 6th Edition," 2005. Available at *http://health.gov/dietaryguidelines/dga2005/document/default.htm*.

8. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)." Chapter 8, "Dietary Fats: Total Fat and Fatty Acids," 2002.

9. FDA/CFSAN, Food Labeling: Health Claims; Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease, Regulatory Impact Analysis, FDA–2013–P–0047.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Section 101.75 is amended by revising paragraphs (c)(1) and (c)(2)(ii) to read as follows:

§ 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.

* * * * *

(c) * * *

(1) All requirements set forth in § 101.14 shall be met, except § 101.14(e)(6) with respect to a raw fruit or vegetable.

(2) * * *

(ii) *Nature of the food.* (A) The food shall meet all of the nutrient content requirements of § 101.62 for a "low saturated fat" and "low cholesterol" food.

(B) The food shall meet the nutrient content requirements of § 101.62 for a "low fat" food, unless it is a raw fruit or vegetable; except that fish and game meats (*i.e.*, deer, bison, rabbit, quail, wild turkey, geese, and ostrich) may meet the requirements for "extra lean" in § 101.62.

* * * * *

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29997 Filed 12–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 878, 880, and 895

[Docket No. FDA–2015–N–5017]

RIN 0910–AH02

Banned Devices; Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling. Consequently, FDA is banning these devices.

DATES: This rule is effective on January 18, 2017.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the

heading of this final rule into the "Search" box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael J. Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993, 301–796–6283, email: *michael.ryan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose and Coverage of the Final Rule

Medical gloves play a significant role in the protection of both patients and health care personnel in the United States. Health care personnel rely on medical gloves as barriers against transmission of infectious diseases and contaminants when conducting surgery, as well as when conducting more limited interactions with patients. Various types of powder have been used to lubricate gloves so that wearers could don the gloves more easily. However, the use of powder on medical gloves presents numerous risks to patients and health care workers, including inflammation, granulomas, and respiratory allergic reactions.

A thorough review of all currently available information supports FDA's conclusion that powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove should be banned. FDA has concluded that the risks posed by powdered gloves, including health care worker and patient sensitization to natural rubber latex (NRL) allergens, surgical complications related to peritoneal adhesions, and other adverse health events not necessarily related to surgery, such as inflammatory responses to glove powder, are important, material, and significant in relation to the benefit to public health from their continued marketing. FDA has carefully evaluated the risks and benefits of powdered gloves and the risks and benefits of the state of the art, which includes viable non-powdered alternatives that do not carry any of the risks associated with glove powder, and has determined that the risk of illness or injury posed by powdered gloves is unreasonable and substantial. Further, FDA believes that this ban would likely have minimal economic and shortage impact on the health care industry. Thus, a transition to alternatives in the marketplace should not result in any detriment to public health.

This rule applies to powdered patient examination gloves, powdered surgeon's gloves, and absorbable powder for lubricating a surgeon's glove. This includes all powdered medical gloves except powdered radiographic protection gloves. Because we are not aware of any powdered radiographic protection gloves that are currently on the market, FDA lacks the evidence to determine whether the banning standard would be met for this particular device. The ban does not apply to powder used in the manufacturing process (*e.g.*, former-release powder) of non-powdered gloves, where that powder is not intended to be part of the final finished glove. Finished non-powdered gloves are expected to include no more than trace amounts of residual powder from these processes, and the Agency encourages manufacturers to ensure finished non-powdered gloves have as little powder as possible. In our 2008 Medical Glove Guidance Manual (Ref. 1), we recommended that non-powdered gloves have no more than 2 milligrams (mg) of residual powder and debris per glove, as determined by the Association for Testing and Materials (ASTM) D6124 test method (Ref. 2). The Agency continues to believe this amount is an appropriate maximum level of residual powder. The ban also does not apply to powder intended for use in or on other medical devices, such as condoms. FDA has not seen evidence that powder intended for use in or on other medical devices, such as condoms, presents the same public health risks as that on powdered medical gloves.

B. Summary of the Major Provisions of the Final Rule

In this final rule, FDA is banning the following devices: (1) Powdered surgeon's gloves, (2) powdered patient examination gloves, and (3) absorbable powder for lubricating a surgeon's glove. Because the classification regulations for these device types do not distinguish between powdered and non-powdered versions, FDA is amending the descriptions of these devices in the regulations to specify that the regulations for patient examination and surgeon's gloves will apply only to non-powdered gloves while the powdered version of each type of glove will be added to the listing of banned devices in the regulations.

Many comments requested that FDA revise the scope of the ban to include all NRL gloves. Many comments from industry requested that the proposed effective date be extended beyond 30 days after the date of publication of the final rule. Of the comments that do not support the ban, commenters noted the need for powdered gloves to aid in donning gloves and tactile sense and the reduced risks associated with current powdered gloves that have less powder. The remaining comments are not clearly in support or opposition to the proposal.

C. Legal Authority

Powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove are defined as devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(h)). Section 516 of the FD&C Act (21 U.S.C. 360f) authorizes FDA to ban a device if it finds, on the basis of all available data and information, that the device presents substantial deception or unreasonable and substantial risks of illness or injury, which cannot be corrected by labeling or a change in labeling. This rule amends 21 CFR 878.4460, 878.4480, 880.6250, 895.102, 895.103, and 895.104. FDA's legal authority to modify §§ 878.4460, 878.4480, 880.6250, 895.102, 895.103, and 895.104 arises from the device and general administrative provisions of the FD&C Act (21 U.S.C. 352, 360f, 360h, 360i, and 371).

D. Costs and Benefits

The final rule is expected to provide a positive net benefit (estimated benefits minus estimated costs) to society. Banning powdered glove products is not expected to impose any costs to society, but is expected to reduce the number of adverse events associated with using powdered gloves. The primary public health benefit from adoption of the rule would be the value of the reduction in adverse events associated with using powdered gloves. The Agency estimates maximum total annual net benefits to range between $26.8 million and $31.8 million.

II. Background

A. Need for the Regulation/History of the Rulemaking

On March 22, 2016, FDA issued a proposed rule to ban powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove (81 FR 15173). Section 516(a)(1) of the FD&C Act authorizes FDA to ban a device intended for human use by regulation if it finds, on the basis of all available data and information, that such a device "presents substantial deception or an unreasonable and substantial risk of illness or injury." For a more detailed discussion of the banning standard, we refer you to the preamble of the proposed rule. FDA issued the proposed regulation because it determined that powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling.

The preamble to the proposed rule describes the history of powdered gloves and the citizen petitions received by the Agency that request a ban on powdered gloves. We refer readers to that preamble for information about the development of the proposed rule. The level and types of risk presented by powdered gloves varies depending on the composition and intended use of the glove. In aggregate, the risks of powdered gloves include severe airway inflammation, hypersensitivity reactions, allergic reactions (including asthma), allergic rhinitis, conjunctivitis, dyspnea, as well as granuloma and adhesion formation when exposed to internal tissue. We refer readers to the preamble of the proposed rule for details on the level and types of risks presented by powdered gloves. The benefits of powdered gloves appear to only include greater ease of donning and doffing, decreased tackiness, and a degree of added comfort, which FDA believes are nominal when compared to the risks posed by these devices.

The state of the art of both surgeon's and patient examination gloves includes non-powdered alternatives that provide similar performance as the various powdered glove types do. That is, there are many non-powdered gloves available that have the same level of protection, dexterity, and performance. Thus, based on a careful evaluation of the risks and benefits of powdered gloves and the risks and benefits of the current state of the art, which includes readily available alternatives that carry none of the risks posed by powdered gloves, FDA has determined that the standard to ban powdered gloves has been met, and that it is appropriate to issue this ban.

Finally, as discussed in the proposed rule, FDA also determined the ban should apply to devices already in commercial distribution and devices already sold to the ultimate user, as well as to devices that would be sold or distributed in the future (see 21 CFR 895.21(d)(7)). This means that powdered gloves currently being used in the marketplace would be subject to this ban and adulterated under section 501(g) of the FD&C Act (21 U.S.C. 351(g)), and thus subject to enforcement action.

B. Summary of Comments to the Proposed Rule

The Agency requested public comments on the proposed rule, and the comment period closed on June 20, 2016. The Agency received approximately 100 comment letters on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from a cross-section of patients and consumers, medical professionals, device manufacturers, and professional and trade associations. A majority of the comments supported the objectives of the rule in whole or in part, while a minority of the comments opposed the objectives of the rule. Some comments suggested changes to specific elements of the proposed rule or requested clarification of matters discussed in the proposed rule. See Section IV for the description of comments on the proposed rule and FDA's responses.

C. General Overview of the Final Rule

FDA published a proposed rule to ban powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove, because FDA determined that these devices present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling (81 FR 15173).

In this final rule, FDA is banning the following devices: (1) Powdered surgeon's gloves (21 CFR 878.4460), (2) powdered patient examination gloves (21 CFR 880.6250), and (3) absorbable powder for lubricating a surgeon's glove (21 CFR 878.4480). Because the classification regulations for these device types do not distinguish between powdered and non-powdered versions, FDA is amending the descriptions of these devices in the regulations to specify that the regulations for surgeon's gloves (21 CFR 878.4460) and patient examination gloves (21 CFR 880.6250) will apply only to non-powdered gloves while the powdered version of each type of glove will be added to 21 CFR part 895, subpart B—Listing of Banned Devices.

D. Clarifying Changes to the Rule

While FDA believes that the preamble to the proposed rule was clear that the proposed ban would apply to all powdered surgeon's gloves and all powdered patient examination gloves, in reviewing the terminology used in the proposed additions to 21 CFR part 895, FDA determined that term "synthetic latex" would not cover every type of non-NRL material that is used to manufacture powdered gloves. It was not FDA's intent to limit the ban to only powdered NRL and powdered synthetic latex gloves, and we believe that this intent was clear from the content of the preamble to the proposed rule, which stated that the ban "would apply to all powdered gloves except powdered radiographic protection gloves." As such, FDA has now revised the identification in this final rule to clarify that the ban applies to all powdered surgeon's gloves and powdered patient examination gloves without reference to the type of material from which they are made. Additionally, the identification of non-powdered surgeon's gloves and non-powdered patient examination gloves is also being revised to remove reference to material.

III. Legal Authority

Powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove are defined as medical devices under section 201(h) of the FD&C Act (21 U.S.C. 321). Section 516 of the FD&C Act (21 U.S.C. 360f) authorizes FDA to ban a device if it finds, on the basis of all available data and information, that the device

presents substantial deception or unreasonable and substantial risks of illness or injury, which cannot be corrected by labeling or a change in labeling. This rule amends §§ 878.4460, 878.4480, 880.6250, 895.102, 895.103, and 895.104. FDA's legal authority to modify §§ 878.4460, 878.4480, 880.6250, 895.102, 895.103, and 895.104 arises from the device and general administrative provisions of the FD&C Act (21 U.S.C. 352, 360f, 360h, 360i, and 371).

IV. Comments on the Proposed Rule and FDA's Responses

A. Introduction

We received approximately 100 comment letters on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from a cross-section of patients and consumers, medical professionals, device manufacturers, and professional and trade associations. A majority of the comments supported the objectives of the rule in whole or in part, while a minority of the comments opposed the objectives of the rule. Some comments suggested changes to specific elements of the proposed rule or requested clarification of matters discussed in the proposed rule.

We describe and respond to the comments in section IV.B through E. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of General Comments and FDA Response

Many comments made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) Many comments support the proposed ban on powdered patient examination gloves and powdered surgeon's gloves. These comments from individual consumers, health care professionals, academia, and industry highlight several risks of the continued use of powdered gloves, including, among others, allergic reactions, post-operative adhesions, and delayed wound healing.

(Response 1) FDA agrees with these comments. After further review of all available information and the comments submitted to the proposed rule, FDA has concluded that the public's exposure to the risks of powdered gloves is unreasonable and substantial in relation to the nominal public health benefit derived from the continued marketing of these devices, especially when considering the benefits and risks posed by readily available alternative devices. Therefore, FDA has determined that the standard for a ban on these devices has been met.

C. Description of Comments That Oppose the Regulation and FDA Response

FDA received some comments that oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves for various reasons. We address each of these reasons for opposition in this section. After reviewing these comments, FDA has determined that the standard to ban powdered gloves has been met, and that it is appropriate to issue this ban. We are finalizing the ban with only clarifying changes.

(Comment 2) Comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves because of difficulty donning or doffing non-powdered gloves. Two commenters specifically discuss hyperhidrosis with claims that it can add to the difficulty donning and doffing non-powdered gloves. One commenter has asserted that double-gloving is more difficult when using non-powdered gloves.

(Response 2) As described in the preamble of the proposed rule, we have concluded that the benefit of ease of donning or doffing powdered gloves is generally nominal (Ref. 3) in comparison to the risks posed by the continued marketing of powdered gloves, which, among others, include severe airway inflammation, hypersensitivity reactions, and allergic reactions (including asthma). Also, as noted in the proposed rule, a study of various brands of powdered and non-powdered NRL gloves by Cote et al. found that there are non-powdered latex gloves that are easily donned with wet or dry hands with relatively low force compared to the forces required to don powdered latex examination gloves (Ref. 3). Thus, FDA has considered ease of donning and doffing as a benefit as it applies within the banning standard, and has determined that the standard is met.

(Comment 3) Comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves because of difficulty donning non-powdered gloves, leading to greater propensity of non-powdered gloves to tear. Some of these comments express concern that the reduced ability to separate the opening of a non-powdered glove or the greater propensity of non-powdered gloves to tear could potentially lead to a higher degree of contamination and post-procedure infections.

(Response 3) FDA disagrees with the assertion that non-powdered gloves have a higher propensity to tear and thus disagrees that use of non-powdered gloves presents a greater risk of contamination, post-procedure infections, or exposure of the user to blood. FDA does not believe there is compelling evidence to support the assertion that non-powdered gloves have a higher propensity to tear. Korniewicz, et al., determined that the presence of powder did not affect the durability of gloves or enhance glove donning (Ref. 4). Although Kerr, et al., identified a statistically significant difference in the durability of non-powdered vinyl gloves compared to powdered vinyl gloves, this difference may be attributed to glove type, manufacturer, and the fingernail length of users rather than the presence or absence of powder (Ref. 5). This study also found that vinyl gloves in general are less durable and have a greater propensity to tear compared to nitrile, neoprene, and latex gloves. Furthermore, as discussed in the response to comment 4, several studies have found that alternatives to non-powdered NRL gloves, such as nitrile and neoprene gloves, offer the same level of protection against contamination and exposure to blood as powdered NRL gloves (Refs. 5, 6, 7, 8, 9, and 10). Therefore, FDA has determined that suitable alternatives to powdered gloves are readily available in the marketplace.

(Comment 4) Commenters oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves because the fit of powdered gloves is more comfortable than non-powdered gloves. Some of these comments assert that the reduced fit of non-powdered gloves inhibits the tactile sensation necessary to perform medical procedures.

(Response 4) FDA disagrees with the assertion that non-powdered gloves inhibit the tactile sensation necessary to perform medical procedures. The ban does not include non-powdered NRL gloves, which offer the same

performance characteristics of powdered NRL gloves, and several studies have found that alternatives, such as nitrile and neoprene gloves, offer the same level of protection, dexterity, and performance as NRL gloves (Refs. 5, 6, 7, 8, 9, and 10). Furthermore, the numerous risks posed by the continued marketing of powdered gloves outweigh the benefit of whatever additional level of comfort is provided from using powdered gloves instead of the non-powdered alternatives that carry none of these risks.

(Comment 5) Some comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves, citing a lack of scientific evidence that gloves with reduced powder content, as those in use today, have the same risks as previously used gloves that had higher powder content.

(Response 5) FDA agrees that the maximum residual level of powder on powdered gloves is less than earlier types of powdered gloves. Historically, powdered medical gloves contained powder levels ranging from 50 to over 400 mg of powder per glove. Effective in 2002, the ASTM International recommended limits on powder levels is 15 mg per square decimeter for surgical gloves (ASTM D3577–2001) (Ref. 11) and 10 mg per square decimeter for patient examination gloves (ASTM D3578) (Ref. 12). As a result, FDA believes that gloves in use after 2002 follow these recommended limits and generally have lower powder content than earlier types of powdered gloves. Even so, several studies indicate that gloves with reduced powder levels continue to present unreasonable and substantial risks to patients and health care workers. For instance, a study conducted on the incidence of skin reactions for Greek endodontists from 2006 to 2012 found that glove powder accounted for the majority of skin reactions, and the replacement of powdered NRL gloves with non-powdered gloves resolved the majority of the adverse reactions (Ref. 13). Similarly, the risks of powdered gloves persist in non-clinical studies using gloves with reduced powder content, as demonstrated by the 2013 finding that surgeries performed with powdered gloves increased the number, density, and fibrotic properties of peritoneal adhesions in rats compared with surgeries performed with non-powdered gloves (Ref. 14). Also, the reduction in cases of NRL-induced occupational contact urticaria coincided with French hospitals transitioning to non-powdered gloves after 2004–2005 (Ref. 13). Finally, FDA is not aware of any report in the literature that supports the assertion that currently marketed powdered gloves with lower powder content reduce the risks presented by powdered gloves (Ref. 15). In summary, FDA concludes that the risks of powder continue to be unreasonable and substantial for currently marketed powdered gloves despite lower powder content than previous generations of powdered gloves.

(Comment 6) Two comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves, because the commenters believe a warning on the risks of powdered gloves is sufficient to mitigate the risks posed by these devices.

(Response 6) As described in Section IV of the proposed rule, FDA has determined that no change in labeling could correct the risk of illness or injury presented by the continued use of these devices. Powdered gloves have additional or increased risks to health compared to non-powdered gloves related to the spread of powder, and the fact that powder-transported contaminants such as NRL allergens can become aerosolized. Exposure to powder or latex allergens presents significant risks to health care workers and patients when inhaled or when exposed to internal tissue during oral, vaginal, gynecological, and rectal exams. Although labeling can raise awareness of these risks, we conclude that labeling cannot effectively mitigate these risks because it cannot prohibit the spread of glove powder or powder-transported contaminants. In addition, an important aspect of these devices is their ability to affect persons other than the individual who decides to wear or use them. For example, patients often do not know the type of gloves being worn by the health care professional treating them, but are still exposed to the potential dangers. Similarly, glove powder's ability to aerosolize and carry NRL proteins exposes individuals to harm via inhalation or surface contact. Thus, some of the risks posed by glove powder can impact persons completely unaware or unassociated with its employment and without the opportunity to consider the devices' labeling. Because of this inherent quality, adequate directions for use or warnings cannot be written that would provide reasonable assurance of the safe and effective use of these devices for all persons that might come in contact with them.

Due to the ability of powder to affect people who would not have an opportunity to read warning labels, and because potential warning labels would raise awareness of the risks, but would not eliminate the risks posed by glove powder, FDA has determined no label or warning can correct the risks posed by these devices.

(Comment 7) One comment opposes the proposed ban on powdered patient examination gloves and powdered surgeon's gloves, because the solvent used to remove powder during the manufacture of non-powdered gloves may cause adverse reactions to the glove user.

(Response 7) FDA is not aware of any report in the literature that supports the assertion of widespread adverse reactions to solvent used in the manufacturing process. Non-powdered patient examination and surgeon's gloves require premarket notification (510(k)) submissions prior to marketing. During the review of these submissions, FDA evaluates the final finished glove, including manufacturing solvents that are present on the final glove. FDA recommends that manufacturers conduct and submit skin irritation and dermal sensitization studies in these submissions to evaluate potential issues with components, including manufacturing solvents (Ref. 1). Although individual hypersensitivity reactions to different materials may occur, FDA has been unable to find evidence in the literature of hypersensitivity to typical glove manufacturing materials other than glove powder or NRL. However, Palosuo, et al., reports that the use of hand sanitizers containing isopropyl alcohol prior to donning gloves could cause dermatitis reaction if the gloves are donned before the alcohol dries (Ref. 16). The occurrence of this reaction is unrelated to the manufacture of non-powdered gloves and unrelated to the use of non-powdered gloves as an alternative to powdered gloves. Given the lack of evidence of adverse reactions to solvents used in the manufacturing of non-powdered gloves, and the established evidence demonstrating the risks of powdered glove use, FDA continues to believe that powdered gloves and glove powder meet the banning standard.

(Comment 8) Several comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves due to the expectation that users will ultimately have to pay more for medical gloves once the ban is finalized, because the cost of non-powdered gloves is currently higher than the cost of powdered gloves.

(Response 8) We do not find any evidence to support the claims that

current prices of non-powdered gloves are significantly higher than powdered gloves. As we stated in the preliminary regulatory impact analysis (PRIA), extensive searches of glove distributor pricing indicate that non-powdered gloves have become as affordable as powdered gloves. Our searches also revealed that the market is saturated with alternatives to powdered gloves, resulting in downward pressure on the prices of non-powdered gloves. In addition, the share of powdered medical gloves sales has been declining since at least 2000 while total sales of all disposable medical gloves have increased (Ref. 17). We would not expect this trend to be occurring without regulatory action if users of disposable medical gloves faced significantly higher prices for switching to non-powdered gloves. We therefore do not find it necessary to update our analysis based on these comments.

(Comment 9) We received one comment that disagrees with our determination that the availability of examination and surgical gloves would not be reduced.

(Response 9) We do not find any evidence to support these claims. As we stated in the PRIA, research shows only 7 percent of total sales of examination and surgical gloves to medical workers were projected to be from powdered gloves in 2010 (Ref. 17). Global Industry Analysts (GIA) projected the share of powdered disposable medical gloves sales to decrease to 2 percent in 2015, while total sales of all disposable medical gloves continue to increase (Ref. 17). We would not expect this trend to be occurring without regulatory action if there were a reduction in the availability of disposable examination and surgical gloves. We therefore do not find it necessary to update our analysis based on these comments.

(Comment 10) Commenters suggest there would be a loss in consumer utility due to the preference some medical workers may have for powdered gloves due to comfort and ease of use.

(Response 10) We stated in the PRIA that the remaining 7 percent continuing to use these powdered gloves may experience utility loss from the removal of powdered gloves from the market (Ref. 17). The potential loss in consumer utility would be due to the perceived loss in comfort from powdered gloves users switching to non-powdered gloves. However, as the GIA report shows, there has been a downward trend in total sales of powdered gloves since at least the year 2000 while total sales of all disposable medical gloves has increased (Ref. 17). We would not expect this trend to be occurring without regulatory action if the loss in consumer utility to current medical workers were substantial. Korniewicz et al. reported no loss in consumer satisfaction in a sample of operating room staff switching to non-powdered surgical gloves (Ref. 4). We have not estimated this potential burden, but the evidence described here suggests that any burden would not be substantial. Further, even having considered that some degree of consumer comfort may be lost by banning powdered gloves, FDA continues to believe that this benefit is considerably outweighed by the numerous risks posed by powdered gloves.

(Comment 11) One comment opposes the proposed ban on powdered patient examination gloves and powdered surgeon's gloves, because the risks identified for powdered gloves are due to contaminants, such as pesticides and herbicides, in the powder that would not be present if the powder were manufactured in the United States.

(Response 11) FDA disagrees with the assertion that contaminated powder is the source of the risks identified for powdered gloves. FDA's proposal to ban powdered gloves and glove powder is based on various studies on the risks of powdered gloves due to the properties of the powder itself. Powdered gloves have additional or increased risks to health compared to non-powdered gloves. For example, powder on NRL gloves can aerosolize latex allergens, resulting in sensitization to latex and allergic reactions. Latex sensitization and allergic reactions are unrelated to any potential presence of manufacturing contaminants, such as pesticides and herbicides. Additional risks of powdered gloves include severe airway inflammation, conjunctivitis, dyspnea, as well as granuloma and adhesion formation when exposed to internal tissue. FDA's assessment of the available literature and information indicates that these risks are attributable to the powder itself, as opposed to any potential presence of manufacturing contaminants, such as pesticides and herbicides.

In addition, the powder used on powdered gloves is required to comply with FDA's Quality System regulation, which includes requirements for quality and inspection for the final finished gloves that protect against the introduction of contaminated devices into commerce. Among other requirements, device manufacturers must establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality (21 CFR 820.70(e)). FDA's Quality System regulation applies to gloves and glove powder sold in the United States, regardless of the manufacturing location.

D. Description of Comments on Scope of Ban and FDA Response

FDA received several comments requesting revision of the scope of the ban. The scope of the proposed ban includes powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove. The glove types include all powdered patient examination and surgeon's gloves, including NRL and synthetic latex gloves. In the following paragraphs, we discuss and respond to comments requesting revision of the scope of the ban. We are finalizing the ban without change to the scope, but clarifying that all powdered patient examination gloves and powder surgical gloves are banned, regardless of the material from which they are made.

(Comment 12) Several comments identify risks that result from the use of powdered and non-powdered NRL gloves. These comments request FDA to extend the ban to all NRL gloves, both powdered and non-powdered.

(Response 12) Unlike with powdered latex gloves, which have the ability to aerosolize glove powder and carry allergenic proteins, FDA believes the risk of allergic reaction to non-powdered NRL gloves, which affects the user and patients in direct contact with the glove, is adequately mitigated through already-required labeling that alerts users to this risk. NRL gloves must include a statement to alert users to the risk of allergic reactions caused by NRL (21 CFR 801.437). Further, several studies have indicated that the use of non-powdered NRL gloves reduces the risk of sensitization to allergenic NRL proteins and the number of allergic reactions experienced by those who are already sensitized (Refs. 18, 19, and 20). FDA believes that these study results, when considered alongside the risk mitigation that follows from FDA's required labeling for NRL products, demonstrates that non-powdered latex gloves can be safely used with appropriate caution for latex-sensitive patients and health care workers. Therefore, FDA has determined not to ban the use of all NRL gloves.

(Comment 13) Several comments raise the issue of life threatening latex allergy events that result from various uses of NRL gloves including food preparation and food service. Several of these comments assert that the Agency should broaden the scope of the ban to cover all

NRL gloves for all uses including food preparation and food service.

(Response 13) We have concluded that it is not appropriate to address a proposal to ban gloves used for food preparation because these gloves do not meet the definition of a device under section 201(h) of the FD&C Act and are thus not subject to section 516 of the FD&C Act (21 U.S.C. 360f), which provides the statutory authority to ban devices within FDA's authority to regulate such products.

(Comment 14) One comment asserts that the ban on powdered gloves should not apply to dental practice, because the risks are not applicable to dental practice.

(Response 14) FDA disagrees with the assertion that the risks of powdered gloves are not applicable to dental practice. Dentists and dental patients face the same risks as other medical practices in terms of the potential for powder exposure to open cavities or open wounds, and for powder, if used with NRL gloves, to carry protein allergens. Several studies documenting the risks of powdered gloves in dental practices have been conducted, including Saary, et al., which identified that changing to low-protein and non-powdered NRL gloves reduced NRL allergy in dental students (Ref. 18). In addition, Charous et al., reported in 2000 that a dental office was able to reduce airborne NRL antigen levels to undetectable levels with the exclusive use of non-powdered NRL gloves, permitting a highly sensitized staff member to continue to work there (Ref. 21). These studies, among others (Refs. 13 and 22), indicate that the risks of powdered medical gloves apply to dental practice. Therefore, FDA has determined that the scope of the ban on powdered medical gloves should continue to include powdered gloves used in dental practice.

E. Description of Other Specific Comments and FDA Response

Many comments made specific remarks requesting clarification or revision to the proposed rule. In the following paragraphs, we discuss and respond to such specific comments.

(Comment 15) A number of comments request extension of the effective date of the ban. The proposed rule included a proposed effective date of 30 days after publication of the final rule for all devices, including those already in commercial distribution. The comments suggest a range of effective dates of 90 days to 18 months after publication of the final rule and assert that a longer transition period is necessary to allow existing inventory to flow through the supply chain to providers and patients.

(Response 15) FDA is not extending the effective date of the ban for devices already in commercial distribution. We have concluded that powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling. The continued marketing of these devices beyond the 30 day effective date would allow for the continued sale and purchase of devices that FDA has determined present an unreasonable and substantial risk to patients and health care workers. Therefore, FDA does not believe that it is in the best interest of the public health to extend the effective date for devices already in commercial distribution. In order to minimize the risk of continued exposure of health care workers and patients to these devices, the effective date for devices remains 30 days after the date of publication of this final rule.

(Comment 16) One comment requests that FDA not extend the effective date of the ban to allow companies to deplete their inventory of the devices.

(Response 16) As described in the response to comment 15, FDA agrees that it is in the best interest of the public health to not extend the effective date of the ban for devices already in commercial distribution. Therefore, the effective date of the ban for devices already in commercial distribution remains at 30 days after the date of publication of the final rule.

(Comment 17) A few comments request recommendations on the means of disposal or recycling of powdered gloves.

(Response 17) FDA recommends that unused inventories of powdered medical gloves remaining at domestic manufacturing and distribution locations be disposed of in accordance with standard industry practices. Unused supplies at hospitals, outpatient centers, clinics, medical and dental offices, other service delivery points (nursing homes, etc.), and in the possession of end users, will need to be disposed of according to established procedures of the local community's solid waste management system. Established procedures for these materials typically involve disposal in landfills or incineration. FDA has concluded that this final rule will not have a significant impact on the human environment. (See Section VII. Analysis of Environmental Impact.)

(Comment 18) One comment requests clarification on whether after the effective date of the ban the Agency will permit a manufacturer to export powdered medical gloves that are already physically located at distribution centers in the United States.

(Response 18) After the effective date of this final rule, manufacturers will not be allowed to import powdered medical gloves. However, while powdered medical gloves will be banned in the United States on the effective date of this final rule, manufacturers may export existing inventory of powdered gloves to a foreign country if the device complies with the laws of that country and has valid marketing authorization by the appropriate authority, as described in section 802 of the FD&C Act (21 U.S.C. 382)). If eligible for export under section 802 of the FD&C Act, a device intended for export will not be deemed adulterated or misbranded if it

(A) accords to the specifications of the foreign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

V. Effective Date

This rule is effective January 18, 2017. The effective date of this rule applies to devices already in commercial distribution and those already sold to the ultimate user, as well as to devices that would be sold or distributed in the future. All powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's gloves must be removed from the market upon the effective date of this final rule. Section 501(g) of the FD&C Act (21 U.S.C. 351(g)) deems a device to be adulterated if it is a banned device.

VI. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety,

and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule imposes no new burdens, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The final rule prohibits marketing of powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating surgeon's gloves. The rule does not cover or include powdered radiographic gloves.

The final rule is expected to provide a positive net benefit (estimated benefits minus estimated costs) to society. Banning powdered glove products is not expected to impose any costs to society. Extensive searches of glove distributor pricing indicate that improvements to non-powdered gloves have made these products as affordable as powdered gloves. The ban is expected to reduce the adverse events associated with using powdered gloves. The Agency estimates maximum total annual net benefits to range between $26.8 million and $31.8 million. The present discounted value of the estimated benefits over 10 years ranges from $228.9 million to $270.8 million at a 3 percent discount rate and from $188.5 million to $223 million at a 7 percent discount rate.

FDA has examined the economic implications of the rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. This rule will not impose any new burdens on small entities, and thus will not impose a significant economic impact on a substantial number of small entities.

The full discussion of the economic impacts of the rule, which includes a list of changes made in the final regulatory impact analysis, in accordance with Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act is available at *https://www.regulations.gov* under the docket number (FDA–2015–N–5017) for this rule and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm#* (Ref. 23).

VII. Analysis of Environmental Impact

FDA has carefully considered the potential environmental effects of this final rule and of possible alternative actions. In doing so, the Agency focused on the environmental impacts of its action as a result of disposal of unused powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove that will need to be handled after the rule is finalized.

The environmental assessment (EA) considered each of the alternatives in terms of the need to provide maximum reasonable protection of human health without resulting in a significant impact on the environment. The EA considered environmental impacts related to landfill and incineration of solid waste at municipal solid waste (MSW) facilities nationwide. The selected action, if finalized, will result in an initial batch disposal of unused powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove from user facilities to MSW facilities nationwide, followed by a rapid decrease in the rate of disposal of these devices, as supplies are depleted. The selected action does not change the ultimate disposition of these devices but expedites their rate of disposal and ceases future production. Overall, given the limited number of powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove, currently in commercial distribution, the selected action is expected to have no significant impact on MSW and landfill facilities and the environment in affected communities.

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The Agency's finding of no significant impact and the evidence supporting that finding, contained in an EA, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday (Ref. 24).

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, FDA is not required to seek clearance by Office of Management and Budget under the Paperwork Reduction Act of 1995.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov*. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

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List of Subjects

21 CFR Parts 878 and 880

Medical devices.

21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 878, 880, and 895 are amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Amend § 878.4460 by revising the section heading and paragraph (a) to read as follows:

§ 878.4460 Non-powdered surgeon's glove.

(a) *Identification.* A non-powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A non-powdered surgeon's glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

* * * * *

§ 878.4480 [Removed]

■ 3. Remove § 878.4480.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 4. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 5. Amend § 880.6250 by revising the section heading and paragraph (a) to read as follows:

§ 880.6250 Non-powdered patient examination glove.

(a) *Identification.* A non-powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A non-powdered patient examination glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

* * * * *

PART 895—BANNED DEVICES

■ 6. The authority citation for part 895 continues to read as follows:

Authority: 21 U.S.C. 352, 360f, 360h, 360i, 371.

■ 7. Add § 895.102 to read as follows:

§ 895.102 Powdered surgeon's glove.

(a) *Identification.* A powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A powdered surgeon's glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

■ 8. Add § 895.103 to read as follows:

§ 895.103 Powdered patient examination glove.

(a) *Identification.* A powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A powdered patient examination glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

■ 9. Add § 895.104 to read as follows:

§ 895.104 Absorbable powder for lubricating a surgeon's glove.

Absorbable powder for lubricating a surgeon's glove is a powder made from cornstarch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove. The device is absorbable through biological degradation.

Dated: December 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30382 Filed 12–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2015–N–0701]

General Hospital and Personal Use Devices: Renaming of Pediatric Hospital Bed Classification and Designation of Special Controls for Pediatric Medical Crib; Classification of Medical Bassinet

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to rename pediatric hospital beds as pediatric medical cribs and establish special controls for these devices. FDA is also establishing a separate classification regulation for medical bassinets, previously under the pediatric hospital bed classification regulation, as a class II (special controls) device. In addition, this rule continues to allow both devices to be exempt from premarket notification and use of the device in traditional health care settings and permits prescription use of pediatric medical cribs and bassinets outside of traditional health care settings.

DATES: This order is effective on January 18, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–6283.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose and Coverage of the Final Rule

Pediatric medical cribs that meet the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(h)) (referred to as pediatric medical cribs or cribs intended for medical purposes) (product code FMS) are regulated by FDA and will have to comply with the special controls identified in this rule for pediatric medical cribs. Cribs that do not meet the device definition (referred to as cribs for non-medical purposes) must meet the Consumer Product Safety Commission's (CPSC's) regulations and guidelines.

In the **Federal Register** of December 28, 2010 (75 FR 81766), the CPSC issued a final rule prohibiting the use of the drop-side rail design for non-medical cribs in consumer households as of June 28, 2011. CPSC's rule established new standards for full-size and non-full-size cribs intended for non-medical purposes, which effectively prohibited the manufacture or sale of cribs intended for non-medical purposes with a drop-side rail design in households, child care facilities, family child care homes, and places of public accommodation. This rule did not affect pediatric medical cribs regulated by FDA, which typically contain a drop-side rail design that includes movable and latchable side and end rails. Although drop-side cribs intended for non-medical purposes are now prohibited, there is still a need for pediatric medical cribs with drop-side rails inside and outside of traditional health care settings. Pediatric medical cribs with drop-side rails are extremely helpful for patient care in hospital settings and even outside of traditional health care settings, such as day care centers caring for infants and children with disabilities, because they allow parents and care givers easy access to children to perform routine and emergency medical procedures, including, but not limited to, cardiopulmonary resuscitation (CPR), blood collection, intravenous (IV) insertion, respiratory care, and skin care. These drop-side rail cribs also make it easier for hospital staff to facilitate safe patient transport and reduce the chance of care giver injury.

Over the last 5 years, FDA has received over 500 adverse event reports, or Medical Device Reports (MDRs), associated with open pediatric medical cribs, through the Agency's Manufacturer and User Facility Device Experience (MAUDE) database. There were adverse event reports of serious injuries, including reports of entrapment, which were predominantly entrapments of extremities (legs or arms). The majority of MDRs for medical cribs were for malfunctions such as drop-side rails not latching or lowering, brakes not holding, wheels or casters breaking, and where applicable, scales not reading correct weights. As a result of the risks to health and need for continued use of pediatric medical cribs in traditional health care settings and non-traditional settings, FDA is revising the identification for § 880.5140 (21 CFR 880.5140) to include only pediatric

EXHIBIT 26

CANCER PREVENTION COALITION

520 NORTH MICHIGAN AVENUE • SUITE 410 CHICAGO, IL 60611 • 312-467-0600 • FAX 312-467-0599

RCL NOV 14 1994

TS9725

November 10, 1994

Ralph Larson
C.E.O.
Johnson & Johnson, Inc.
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Dear Mr. Larson,

A wide range of scientific studies dating back to the 1960s shows conclusively that the frequent use of talcum powder in the genital area poses a serious risk of ovarian cancer.

Dr. Bernard Harlow, a leading ovarian cancer researcher from Harvard Medical School, published a comprehensive study in 1992 of the link between talc and ovarian cancer. The study found a threefold increase of ovarian cancer in women who used talc in the genital area as a daily habit. Dr. Harlow warns:

> "...given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided, particularly those with limited benefits. For this reason, we discourage the use of talc in genital hygiene, particularly as a daily habit."

Furthermore, the U.S. National Toxicology Program has recently confirmed that talc is carcinogenic.

This year alone, 14,000 women will die from ovarian cancer, giving it the fourth highest women's cancer death rate. Ovarian cancer is very difficult to detect and has a low survival rate. Researchers can attribute only 3% of all ovarian cancer cases to family history of the disease.

Women have the unarguable right to know of this information. The Cancer Prevention Coalition urges you to immediately withdraw your talc products from the market and substitute them with a safer alternative, such as cornstarch. At the very minimum, we urge Johnson & Johnson to label its talcum powder products with information about the ovarian cancer risk they pose.

Over the next several months, the Cancer Prevention Coalition will be implementing a consumer labeling initiative to inform shoppers of the presence of avoidable carcinogens in cosmetics and other consumer products and enable them to shop for alternatives. We would greatly welcome your joining us in this effort on behalf of your customers.

If you have any questions, you can reach the Cancer Prevention Coalition at the above address and phone number. Thank you for your cooperation.

Sincerely,

Samuel S. Epstein, M.D.
Chair

EXHIBIT 27

JERSEY JOURNAL (CITY EDITION)
JERSEY CITY, NJ
DAILY 65,000
WEDNESDAY
APR 17 1996

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Women's health concerns prompt condom makers to stop using talc

By Marie McCullough
Knight-Ridder Newspapers

Concern about talc as an ovarian carcinogen goes back 50 years in the medical literature. By the 1970s, evidence was mounting that talc particles might migrate into a woman's fallopian tubes where they could cause scarring and irritation of the ovaries. Scientists believed in some cases that the scarring led to infertility or cancer.

Candace Sue Kasper believes "safe sex" should be as safe for women as for men.

So early this year, the Dallas skin pathologist began urging – some would say badgering – condom-makers and the federal Food and Drug Administration to stop the little-known practice of coating condoms with talc.

Talc, a powder made from the rocklike mineral magnesium silicate, is an excellent dry lubricant, but can scar soft tissues inside the body, where it does not dissolve. In women, body powders containing talc have been linked to infertility and ovarian cancer.

Kasper's campaign apparently worked.

"We've requested U.S. manufacturers to cease using (talc) and, in fact, all have agreed not to use it in manufacturing condoms," FDA spokesman Arthur Whitmore said in December.

Carter-Wallace, which makes Trojans and claims 60 percent of the American condom market, said in a statement that "to allay any possible concern," it has "discontinued the use of talc in its condom manufacturing process."

'Why take the risk?'

Kasper, 46, feels vindicated, but not victorious. She said an FDA official told her the agency has not been proven to be harmful – because cornstarch is a cheap, safe alternative.

"We'll probably never know for sure" that condom talc is unsafe, he said. "But why take the risk? Cornstarch does just fine and doesn't pose risks. I think it's prudent for manufacturers" to switch.

Indeed it is, said Ansell Inc. of Eatontown, N.J., which makes LifeStyle condoms and has about a quarter of the American condom market. Ansell switched from talc to cornstarch in January 1994.

"We knew surgical glove talc was a problem, so we figured there might be a problem with condoms," said Milt Hinsch, Ansell's vice president of technical affairs. "Whether it's rational or scientific, you just have to say, 'Let's not argue about it. Let's just do it.' "

In 1990, the FDA asked manufacturers to voluntarily stop putting talc on surgical gloves amid mounting scientific evidence that it caused adhesions in surgical patients. At the same time, the agency evaluated talc on condoms, but concluded the amount was insignificant and did not pose problems, said FDA spokeswoman Sharon Snider.

Talc in breast tissue

Kasper's concern about condoms arose after she and a colleague, Dallas plastic surgeon Preston Chandler, discovered talc in the hardened tissue surrounding breast implants that had been removed from women.

In a 1994 journal article, the two physicians speculated that the talc might have contributed to the hardening and that it came from surgical gloves. They also speculated that talc might play a role in the autoimmune symptoms that are the subject of numerous breast implant lawsuits.

Curious to see whether other products were dusted with talc, Kasper and Chandler bought condoms, pacifiers and baby-bottle nipples in 1994 at Dallas-area stores, then scrutinized them under a microscope. The nipples and pacifiers appeared clean, but all eight brands of American-made and foreign-made condoms had varying amounts of talc, cornstarch and, in some cases, substances such as sand, silicone dioxide or club moss spores (an outmoded lubricant that also causes scarring in soft tissues).

Kasper and Chandler wrote to the condom manufacturers, several of which responded that they did not use talc in their production process. Carter-Wallace did not respond to them, Kasper said.

Only one manufacturer, Ansell, backed up its claim to be talc-free, Kasper said. She examined Ansell condoms made after January 1994 and found cornstarch, not talc.

She and Chandler also expressed their concern to the FDA, which thanked them for their information – but didn't say it would take any action.

"Largely, we've been ignored," said Kasper, who has a private pathology practice and is a staff physician at Baylor Medical Center. "Fortunately, my livelihood doesn't depend on this. I've done this on my own time and money."

Journal spurred action

What spurred the FDA to act was a letter to the editor from Kasper and Chandler, published in the March 15 Journal of the American Medical Association, warning about talc on condoms. The FDA's office of device evaluation wrote to four American condom makers, enclosing a copy of the JAMA letter.

"Please let us know if you are using talc in your condom manufacturing process," said the FDA's letter – which did not specifically say to stop using it.

The FDA's Snider said the FDA inspects condoms for holes, but not contaminants, so talc compliance is voluntary.

What's to stop condom-makers from returning to talc?

"Right at the moment, legally, nothing," Snider said.

Several manufacturers' spokesmen asserted they did not use talc.

David Mayer, president of the company that distributes Japanese-made Sagami condoms, said the product was lubricated with silicone oil.

"But there is no scientific evidence that talc on condoms does any harm," he said.

Carter-Wallace spokesman Steven Curtis would not say what lubricant the company had substituted for talc.

Neither would Leanne Hand, spokeswoman for London International U.S. Holdings Inc., which distributes Japanese-made condoms including Ramses.

The company "did use talc until about 1989," she said.

Plaintiff's Exhibit No. P-19
exhibitsticker.com